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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-446]

Schedules of Controlled Substances: Placement of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA] and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. If finalized, this action would make permanent the existing regulatory controls and administrative, civil,

and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA.

DATES: Comments must be submitted electronically or postmarked on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Interested persons may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference “Docket No. DEA-446” on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment.

Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

- *Hearing requests:* All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Lynnette M. Wingert, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by

the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference.

Request for Hearing, or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person’s position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for hearing and waivers of participation must be sent to the DEA using the address information provided above.

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the

Department of Health and Human Services (HHS);¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary for Health of the HHS (Assistant Secretary) and an evaluation of all other relevant data by the DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA.

Background

On April 10, 2017, the DEA published an order in the *Federal Register* amending 21 CFR 1308.11(h) to temporarily place the six synthetic cannabinoids (SCs) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA] and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 82 FR 17119.

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

That temporary scheduling order was effective on the date of publication, and was based on findings by the Acting Administrator of the DEA (Acting Administrator) that the temporary scheduling of these six synthetic cannabinoids (SC) was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), requires that the temporary control of these substances expire two years from the effective date of the scheduling order, which was April 10, 2017. However, the CSA also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, the temporary scheduling of that substance could be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of HHS,² or on the petition of any interested party. An extension of the existing temporary order is being ordered by the Acting Administrator in a separate action, and is published elsewhere in this issue of the *Federal Register*.

The Acting Administrator, on his own motion pursuant to 21 U.S.C. 811(a), is initiating proceedings under 21 U.S.C. 811(a)(1) to permanently schedule 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA. The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these six SCs. On September 27, 2017, the Acting Administrator submitted a request to the Acting Assistant Secretary to provide the DEA with a scientific

² Because the Secretary of HHS has delegated to the Assistant Secretary the authority to make domestic drug scheduling recommendations, for purposes of this proposed scheduling action, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

and medical evaluation of available information and a scheduling recommendation for 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, and in accordance with 21 U.S.C. 811(b) and (c). On March 21, 2019, the Assistant Secretary submitted HHS's scientific and medical evaluation for these six substances to the Acting Administrator. Upon receipt of the scientific and medical evaluation and scheduling recommendation from the HHS, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in accordance with 21 U.S.C. 811(c).

Proposed Determination to Schedule 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA

As discussed in the background section, the Acting Administrator is initiating proceedings, pursuant to 21 U.S.C. 811(a)(1), to add 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA permanently to schedule I of the CSA. The DEA has reviewed the scientific and medical evaluation and scheduling recommendations, received from HHS, and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its proposed scheduling action. Please note that both the DEA 8-Factor and HHS 8-Factor analyses and the Assistant Secretary's March 21, 2019, letter, are available in their entirety under the tab

“Supporting Documents” of the public docket of this action at <http://www.regulations.gov>, under Docket Number “DEA-446.”

1. *The Drug’s Actual or Relative Potential for Abuse:* The term “abuse” is not defined in the CSA. However, the legislative history of the CSA suggests that the DEA consider the following criteria in determining whether a particular drug or substance has a potential for abuse³:

a) *There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or*

b) *There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or*

c) *Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or*

d) *The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.*

HHS noted that people are taking 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA in sufficient amounts to create a health hazard. Adverse effects observed following the ingestion of synthetic cannabinoids, including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, include nausea and vomiting, shortness of breath or depressed breathing, hypertension, tachycardia, chest pain, muscle twitching, acute renal

³ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

failure, anxiety, agitation, psychosis, suicidal ideation, and/or cognitive impairment. SCs like 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are easily accessible and difficult to detect in standard urine drug screens, which contributes to their popularity and high rates of abuse. In addition, poison centers continue to report the abuse of SCs and their associated products demonstrating that these substances remain a threat to both the short- and long-term public health and safety.

In their letter dated March 21, 2019, the HHS stated that there are no Food and Drug Administration (FDA)-approved drug products containing 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in the United States and there appear to be no legitimate sources for these substances as marketed drugs. Because 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are not approved for medical use and are not formulated or available for clinical use, the human use of these substances is assumed to be on an individual's own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer drugs. Further, published scientific and medical literature, and reports from the American Association of Poison Control Centers (AAPCC) and law enforcement indicate that individuals are taking these SCs on their own initiative, rather than on the basis of medical advice of a licensed practitioner.

HHS detailed that 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, similar to schedule I SCs (e.g., JWH-018), bind to and activate the CB1 cannabinoid receptor. As stated by HHS, 5F-ADB, 5F-AMB, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA produced delta-9-

tetrahydrocannabinol (THC)-like discriminative stimulus effects in rats trained to discriminate THC from vehicle control. DEA further notes that in drug discrimination studies conducted under the interagency agreement between DEA and FDA, 5F-APINACA also produced THC-like discriminative stimulus effects in rats trained to discriminate THC from vehicle control.

The abuse of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, similar to schedule I SCs, has been associated with various adverse health effects. As stated by the HHS, it is reasonable to assume that these six SCs have substantial capability to be a hazard to the health of the user and to the safety of the community.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are SCs that have pharmacological effects similar to the schedule I hallucinogen THC and other temporarily and permanently controlled schedule I SCs. HHS reported on in vitro receptor binding and functional assays that were conducted with 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA. In addition, drug discrimination studies using Sprague Dawley rats investigating the THC-like stimulus effects of these SCs have been completed. These results indicate that 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, similar to other schedule I SCs, bind to CB1 receptors, act as agonists at CB1 receptors, and produce THC-like discriminative stimulus effects.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:*

HHS noted that chemically, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, and MDMB-FUBINACA can be described as 3-carboxamide indazole derivatives while MDMB-CHMICA belongs to the 3-carboxamide indol family. The DEA is not aware of any currently accepted medical uses for 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA. As mentioned by the HHS, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have not been approved by FDA for medical use in the United States.

Absent an FDA approval, according to established DEA procedure and case law, “a drug has a currently accepted medical use if all of the following five elements have been satisfied.” (57 FR 10499; March 26, 1992).

- i. The drug’s chemistry must be known and reproducible.
- ii. There must be adequate safety studies.
- iii. There must be adequate and well-controlled studies proving efficacy.
- iv. The drug must be accepted by qualified experts.
- v. The scientific evidence must be widely available.

HHS evaluated these six SCs using this five-part test and determined that none of the six SCs has a “currently accepted medical use” in the United States.

4. *Its History and Current Pattern of Abuse:* All 6 SCs were identified internationally prior to their discovery within the United States. 5F-ADB was first identified in November 2014, in Japan in postmortem samples of an individual who died following use of an herbal product containing this substance. 5F-AMB was first identified in herbal smoking mixtures in Japan between November 2013 and May 2014. 5F-APINACA was

first identified in South Korea beginning in late 2012. ADB-FUBINACA was first reported in the scientific literature in a patent by Pfizer in 2009 (compound 1) followed by popularity in Turkey in 2011 prior to its emergence on the United States illicit drug market in March, 2014. According to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the first seizure of MDMB-CHMICA was on September 12, 2014. Germany also reported 9 deaths and 34 non-fatal intoxications involving MDMB-CHMICA from September 2014 through October 2014. According to the United Nations Office on Drugs and Crime, 40 kilograms of MDMB-CHMICA was identified in a seizure by Luxembourg Customs in December 2014. MDMB-FUBINACA was first identified as “MDMB /N/-Bz F” by Russian media outlets following the reported overdoses of 700 people and 25 deaths in October 2014.

In recent cases of overdoses or deaths, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have been encountered in the form of herbal products, similar to the SCs that have been previously encountered.

5. *The Scope, Duration, and Significance of Abuse:* Following multiple scheduling actions controlling SCs, law enforcement and health care professionals have encountered novel SCs including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA differing only by small structural modifications intended to avoid prosecution while maintaining the pharmacological effects. National Forensic Laboratory Information System (NFLIS⁴) details over 31,512 reports from forensic laboratories identifying 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA,

⁴ NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from U.S. Customs and Border Protection (CBP). NFLIS only includes drug chemistry results from completed analyses.

MDMB-CHMICA and MDMB-FUBINACA for a period from August 2012 through February 2019. In addition, System to Retrieve Information from Drug Evidence (STRIDE⁵) and STARLiMS⁶ have 1,685 reports involving 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA from 2012 through February 2019.

6. *What, if Any, Risk There is to the Public Health:* The HHS and DEA documented multiple cases where 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have been identified in overdoses and/or cases involving death attributed to their abuse. Adverse health effects reported from these incidents involving 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA included nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness, cardio toxicity and/or death. By sharing pharmacological similarities with schedule I substances (THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA, SCs with no approved medical use, pose serious risk to the abuser.

7. *Its Psychic or Physiological Dependence Liability:* As stated by HHS, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have pharmacological profiles that are similar to other schedule I SCs (e.g., JWH-018, XLR11 and AKB-48) and therefore it is reasonable to assume that these six SCs possess

⁵ STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and some local law enforcement agencies.

⁶ STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by DEA laboratories. On October 1, 2014, STARLiMS replaced System to Retrieve Information from Drug Evidence (STRIDE) as the DEA laboratory drug evidence data system of record.

physiological and psychological dependence liability similar to that of these schedule I SCs. There are no clinical studies evaluating psychic or physiological dependence liabilities specific for 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are not immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by the HHS, the HHS's recommendation, and the DEA's own eight-factor analysis, the DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA. As such, the DEA hereby proposes to permanently schedule 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

1. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have a high potential for abuse that is comparable to other schedule I substances such as THC and JWH-018;

2. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA under medical supervision.

Based on these findings, the Acting Administrator of the DEA concludes that methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA] and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA

If this rule is finalized as proposed, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA would continue⁷ to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, or who desires to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, is required to be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823 and in accordance with 21 CFR 1301.71–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-

⁷ 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 82 FR 17119, April 10, 2017.

FUBINACA must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with the DEA to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA must have an initial inventory of all stocks of controlled substances (including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA is required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize

litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Executive Order 13771

This proposed rule does not meet the definition of an Executive Order 13771 regulatory action, and the repeal and cost offset requirements of Executive Order 13771 have not been triggered. OMB has previously determined that formal rulemaking actions concerning the scheduling of controlled substances, such as this rule, are not significant regulatory actions under Section 3(f) of Executive Order 12866.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On

April 10, 2017, the DEA published an order to temporarily place these six SCs in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The DEA estimates that all entities handling or planning to handle these SCs have already established and implemented the systems and processes required to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA. There are currently 28 registrations authorized to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 28 registrations represent 24 entities, of which 14 are small entities. Therefore, the DEA estimates 14 small entities are affected by this proposed rule.

A review of the 28 registrations indicates that all entities that currently handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA. Therefore, the DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 14 affected small entities. Therefore, the DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, the DEA has determined and certifies that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year * * *.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b) unless otherwise noted.

2. In § 1308.11, add paragraphs (d)(73) through (78) and remove and reserve

paragraphs (h)(6) through (11) to read as follows:

§ 1308.11 Schedule I.

* * * *

(d) * * *

(73) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (Other names: 5F-ADB; 5F-MDMB-PINACA).....7034

(74) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (Other names: 5F-AMB).....7033

(75) *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (Other names: 5F-APINACA, 5F-AKB48).....7049

(76) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (Other names: ADB-FUBINACA).....7010

(77) methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (Other names: MDMB-CHMICA, MMB-CHMINACA).....7042

(78) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (Other names: MDMB-FUBINACA).....7020

* * * *

Dated: April 2, 2019.

Uttam Dhillon

Acting Administrator

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